

IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

FILED
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STATE OF TENNESSEE, *ex rel.*
ROBERT E. COOPER, JR., ATTORNEY
GENERAL and REPORTER,

Plaintiff,

v.

BAYER CORPORATION, a foreign
corporation,

Defendant.

No. 07C-227

COMPLAINT

This civil law enforcement proceeding is brought in the name of the State of Tennessee, by and through Robert E. Cooper, Jr., Attorney General & Reporter, pursuant to the Tennessee Consumer Protection Act of 1977 (Tenn. Code Ann. § 47-18-101 *et seq.*) ("TCPA"), the Attorney General's general statutory authority (Tenn. Code Ann. § 8-6-109), the Attorney General's authority at common law, and at the request of Mary Clement, the Director of the Division of Consumer Affairs of the Department of Commerce and Insurance ("Director"). The Attorney General and the Director have reason to believe that the above-named Defendant has violated the TCPA by engaging in unfair and deceptive acts and practices in connection with its marketing and sale of the prescription drug, Baycol, to wit: by failing to adequately warn prescribers and consumers and/or making false, misleading or deceptive representations

regarding the adverse side effects, safety, and efficacy of Bayer's prescription drug, Baycol. Bayer's conduct constitutes unfair and/or deceptive acts and practices in violation of Tenn. Code Ann. §§ 47-18-104 (b) (5), (b) (7) and (b) (27). There is no other civil action between these parties arising out of the same transaction or occurrences as alleged in this Complaint pending in this Court.

THE PARTIES

1. Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General & Reporter, is charged with enforcing the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.*, (hereinafter “the TCPA”), which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Under Tenn. Code Ann. § 47-18-108 (a) (1), the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the TCPA and to secure such equitable and other relief as may be appropriate in each case. The Attorney General is authorized to seek a judgment which enjoins fraudulent or illegal business acts or practices, including but not limited to, any misrepresentation, concealment or suppression of a material fact, and which awards damages, restitution and any other appropriate relief for such acts. *Id.*; Tenn. Code Ann. §§ 47-18-108 (b) (1-4) and (c).

2. Defendant Bayer Corporation (hereinafter “Bayer”) is a corporation organized and existing under the laws of the State of Indiana and is registered to conduct business in the State of Pennsylvania. Bayer is engaged in the trade or commerce of researching, developing, manufacturing, distributing, selling, and promoting drugs for use by Tennessee consumers in treating various illnesses and diseases. Bayer's principal place of business is in the State of

Pennsylvania at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205-9741. Bayer's registered agent in Tennessee is Corporation Service Company, 2908 Poston Avenue, Nashville, TN 37203.

JURISDICTION AND VENUE

3. This Court exercises jurisdiction pursuant to Tenn. Code Ann. § 20-2-201, Tenn. Code Ann. § 20-2-214, Tenn. Code Ann. § 47-18-108 and Tenn. Code Ann. § 47-18-114. The Defendant, through its transactions, is doing business in Tennessee and is subject to jurisdiction through the State's long-arm statute, Tenn. Code Ann. § 20-2-201 *et seq.*, specifically Tenn. Code Ann. § 20-2-214(a)(1), (2), and (6). Pursuant to Tenn. Code Ann. § 20-2-214 (c), a foreign corporation may be subject to jurisdiction based on the actions of an agent.

4. Venue is proper in Davidson County pursuant to Tenn. Code Ann. § 47-18-108 (a) (3) because it is one of the counties in Tennessee where the unfair and deceptive acts and practices alleged in this Complaint have taken place.

FACTUAL ALLEGATIONS

5. Bayer is in the business of, among other things, researching, developing, manufacturing, distributing, selling, and promoting drugs for use in treating various illnesses and diseases.

6. Baycol, a "statin" cholesterol-lowering prescription drug, was approved by the FDA in 1997, and launched in the prescription market by Bayer in May of 1998.

7. While statin drugs carry a known risk of myopathy and rhabdomyolysis, the risk of these adverse side effects with Baycol was significantly higher compared to other statins,

particularly at higher doses and when combined with genfibrozil, another cholesterol-lowering drug.

8. Bayer failed to adequately warn prescribers and consumers of the greater risk of adverse side effects of Baycol, including but not limited to myopathy and rhabdomyolysis.

9. Bayer has made or caused to be made, directly or indirectly, explicitly or by implication, representations and omissions which are material, false and likely to mislead, including, but not limited to the following:

a. That Baycol did not pose an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs in mono-therapy; and

b. Failure to adequately disclose that use of genfibrozil with Baycol is contraindicated.

10. Contrary to Bayer's representations and omissions, Bayer:

a. Knew or had reason to know that Baycol posed an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs in mono-therapy; and

b. Knew or had reason to know that Baycol posed an increased risk of myopathy and rhabdomyolysis as compared to other statin drugs when prescribed in combination with genfibrozil.

11. As a result of Bayer's misrepresentations and omissions, consumers of Baycol, including state agencies that purchased or paid for Baycol pursuant to prescription drug programs, were not aware of the increased risk of myopathy and rhabdomyolysis associated with the use of Baycol.

**CAUSE OF ACTION UNFAIR, UNCONSCIONABLE, OR
DECEPTIVE ACTS OR PRACTICES**

12. Section 47-18-108 (a) (1) of the Tennessee Code Annotated, authorizes the Attorney General to bring an action to enjoin a defendant from engaging in a method, act, or practice that is unlawful under the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq.*

13. By engaging in the acts and practices described above, Bayer has engaged in unfair, unconscionable, or deceptive acts and practices in violation of Tenn. Code Ann. §§ 47-18-104 (b) (5), (b) (7) and (b) (27).

14. Bayer engaged in the acts and practices described above when it knew, or should have known, that its conduct was unfair or deceptive in violation of Tenn. Code Ann. §§ 47-18-104 (b) (5), (b) (7) and (b) (27).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General & Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law and this Court's equitable powers, prays that an order and judgment be entered and that such orders and injunctions be issued without bond pursuant to Tenn. Code Ann. § 47-18-108 (4);

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. § 47-18-116;

2. That process issue and be served upon Defendant, requiring it to appear and answer this Complaint;

3. That this Court adjudge and decree that the Defendant has engaged in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977;

4. That this Court permanently enjoins Bayer from engaging in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977:

A. That this Court permanently enjoins Bayer from making any false, misleading or deceptive representation regarding any of its pharmaceutical or biological products in violation of all applicable laws and regulations;

B. That this Court directs Bayer to comply with all applicable laws and regulations relating to the marketing, sale, and promotion of its pharmaceutical and biological products;

C. That this Court directs Bayer to establish and maintain a clinical trial registry upon which Bayer shall post summaries of all clinical study reports for all studies conducted by Bayer on its pharmaceutical or biological products;

D. That this Court directs Bayer to pay civil penalties for each violation of Tenn. Code Ann. §§ 47-18-104 (b) (5), (b) (7) and (b) (27), of not more than one thousand dollars (\$1,000.00) per violation to the State as provided by Tenn. Code Ann. § 47-18-108(b)(3);

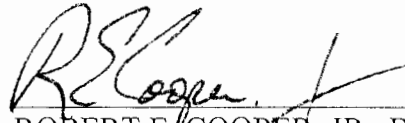
E. That this Court awards Plaintiff costs and attorneys fees, pursuant to Tenn. Code Ann. § 47-18-108 (b) (4);

F. That all costs in this case be taxed against Defendant; and

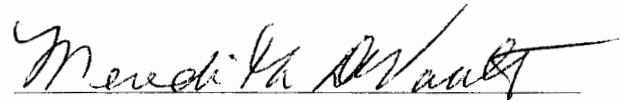
G. That this Court grant Plaintiff such other and further relief as this Court deems just and proper. in accordance with Tenn. Code § 47-18- 108 (b) (3).

RESPECTFULLY SUBMITTED,

STATE OF TENNESSEE



ROBERT E. COOPER, JR., B.P.R. 010934
Attorney General & Reporter



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I hereby certify that this is a true copy
of original instrument filed in my office
this 23 day of Jan 20 07
RICHARD R. ROOKER Clerk
By C. Hef
Deputy Clerk

CERTIFICATION

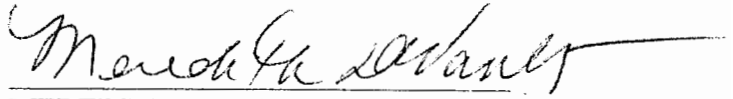
This is to certify that a copy of the foregoing has been mailed, certified return receipt requested, this 23rd day of January, 2007, postage prepaid, to:

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